Device for providing spongy bone with bone substitute and/or bone reinforcing material, bone substitute and/or bone reinforcing material and method.

The present invention relates to a device for providing spongy bone with bone substitute and/or bone reinforcing material, wherein at least one perforating device is provided for making at least one hole in the spongy bone and wherein at least one flushing or rinsing device is provided for flushing or rinsing the hole with a rinsing agent. The invention further relates to a bone substitute and/or bone reinforcing material and a method.

Vertebroplasty is a technique according to which biocompatible material is injected into a spongy vertebra. After some time, the injected material hardens, whereby an inner support is obtained for fixing the vertebra and thereby alleviate pain and reduce the risk of vertebral collapse.

The material is injected into the vertebra through a needle and in doing so, it is necessary to subject the material to high pressure, often one or more MPa. Hereby, there is an obvious risk that tissue material, e.g. blood and fat, in the vertebra is pressed out into the blood vessels or into fracture gaps such that said material can affect adjacent nerves. There is also an obvious risk that the injected material is pressed out into fracture gaps or into adjacent tissue. This is well known and the material and fat being pressed out can reach the blood vessels and the lungs, resulting in a poorer oxygenation, blood pressure reduction and, in exceptional cases, death.

By inserting an extra needle into the vertebra, the risk of leakage (note publications in the enclosed reference list, point 1 and 2, in the end of the description). Normally, this extra needle is left open or preferably connected to a suction hose for generating a suction effect (note publication in the enclosed reference list,

point 3). However, any decisive effect is not reached with the prior art.

Various hole making and rinsing devices for making holes in and rinsing of vertebrae are known from e.g. US 6 440 138, US 6 716 216, US 6 719 761 and US 6 740 090, but none of these publications describes generation of a vacuum in the vertebrae for providing safe suction of bone substitute and/or bone reinforcing material into said vertebrae.

The object of the present invention has been to eliminate the abovementioned problem and this is arrived at while the invention has been given the characterizing features of each of subsequent claim 1, 44, 51, 53, 56 and 58.

By making a hole in the spongy bone and rinse it, tissue material and other material can be flushed away from the hole and the sides thereof, such that said sides get rough or uneven surfaces with depressions into which the bone substitute and/or bone reinforcing material can be brought to penetrate by generating a vacuum in the hole and without risking that said bone substitute and/or bone reinforcing material penetrates into the blood paths.

The invention will be further described below with reference to the accompanying drawings, in which

fig. 1 is a schematic view of a device according to the invention when making a hole in a spongy vertebra shown in section;

fig. 2 illustrates parts of the device of fig. 1 during flushing or rinsing of the hole made in the spongy vertebra;

fig. 3 illustrates parts of the device according to the invention during suction of bone substitute and/ /or bone reinforcing material into the vertebra;

fig. 4 is a sectional view of a spongy vertebra in which bone substitute and/or bone reinforcing material

has been injected with pressure through a needle according to prior art; and

fig. 5 is a sectional view of a spongy vertebra into which bone substitute and/or bone reinforcing material has been sucked by means of a device according to the invention.

In the figures, different parts of a device for preparing spongy bone 1, e.g. a vertebra 2, to receive bone substitute and/or bone reinforcing material 3, and for locating said material in said vertebra is schematically illustrated. Said device comprises at least one perforating device 4 for making at least one hole 5 in the vertebra 2, at least one flushing or rinsing device 6 for flushing or rinsing said hole with rinsing agent 7 and at least one supply device 8 which permits suction and/or insertion of bone substitute and/or bone reinforcing material 3 into the vertebra.

At least one vacuum source 9 is provided to generate a vacuum in the hole 5 in the vertebra 2 for sucking and/or facilitate insertion of bone substitute and/or bone reinforcing material 3 into said vertebra.

The perforating device 4 can be designed in many different ways and so can also the rinsing device 6. At the exemplary embodiment of figs. 1 and 2, the perforating and rinsing devices 4, 6 are combined to a device 10 including an outer tube member 11 which can be located at the vertebra 2. In the tube member 11 there is provided a perforating means 12 which is movable relative to said tube member in coaxial and/or rotary direction. The perforating means 12 has and/or cooperates with a perforating member 13 which can be designed in many ways. As an example of a perforating member 13, it is shown an end portion of the perforating means 12 which can be retracted into the outer tube member 11 when this is located at the vertebra 2 and which is bent when it is expelled out of said pipe member. When the perforating

means 12 is rotated, the bent perforating member 13 will make the hole 5 in the vertebra 2.

The movements of the perforating means 12 can be obtained by means of a drive unit 14 of a suitable type.

At the exemplary embodiment, the perforating means 12 is designed as an inner tube member 15. A rinsing agent container 16 is connected to this inner tube member 15 through a connecting device 17 which permits feeding of rinsing agent 7 from the container 16 into the inner tube member 15 irrespective of whether said inner tube member is rotatable or not. Alternatively, the rinsing agent container 16 may be connected to the outer tube member 11 and the collecting device 27 and the vacuum source 9 to the inner tube member 15, such that the outer tube member 11 can lead rinsing agent 7 into the hole 5 and be sucked out of said hole through the inner tube member 15. The perforating device 4 is used preferably for making at least two holes 5 in the vertebra 2. These holes 5 are located such that they communicate with each other either by extending into each other (as is illustrated in fig. 3) or by having spongy bone 1 between them since such bone is pervious to air and can be provided with bone substitute and/or bone reinforcing material 3.

The vacuum source 9 is provided to suck rinsing agent 7 through the hole 5 and it is preferably connected to the outer tube member 11 for sucking, through said outer tube member, rinsing agent 7 and tissue material and other material out of said hole 5.

Between the outer tube member 11 and the vacuum source 9 there is preferably a collecting device 27 for collecting rinsing agent 7 and tissue material and other material brought along therewith out of the hole 5.

The rinsing device 6 is preferably provided also to flush or rinse the sides 5a of the hole 5 such that depressions 5b and similar are formed therein while tissue material and other material is flushed off said

sides. This is advantageous since bone substitute and/ /or bone reinforcing material 3, by means of the vacuum generated in the hole 5, can be brought to penetrate into the depressions 5b.

At the embodiment illustrated in fig. 3, the outer tube member 11 has its equivalent in a first cannula or needle 19 which can cooperate with a perforating device (not shown) for making a first hole 5 in the vertebra 2. A second cannula or needle 20 is connected to a vacuum source 9 and this second cannula can also cooperate with a perforating device (not shown) for making a second hole 5 in the vertebra 2.

The supply device 8 illustrated in fig. 3 may have a container 18 for mixing various components for production of bone substitute and/or bone reinforcing material 3 and/or for storage thereof. The container 18 is connected or connectable to a first cannula or needle 19 which can be inserted into the vertebra 2 and which is adapted to lead bone substitute and/or bone reinforcing material 3 into the holes 5 in the vertebra 2. A second cannula or needle 20 can be inserted into the vertebra 2 and is connected to the vacuum source 9, which is adapted to generate a vacuum in the holes 5 such that bone substitute and/or bone reinforcing material 3 is sucked into said holes and/or for facilitating insertion or feeding of said material into said holes.

The vacuum source 9 can be an injector pump 21 which is run or driven by a suitable compressed medium from a compressed-medium device 22. The injector pump 21 may e.g. be driven by compressed air and connected, through a compressed-air conduit 23, to a compressed-medium device 22 in the form of a compressed-air device. This device may be built into a hospital or other locality in which the injector pump 21 shall be used. Alternatively, the injector pump 21 can be run or driven by another commercially available gas as is indicated with broken lines in fig. 3.

The compressed-medium device 22 can operate the injector pump 21 with a compressed-medium pressure of 4,5 - - 8,5 bar and the injector pump 21 may be of a type which is placed on the floor and which has a foot pedal 24 for its operation. Thus, the injector pump 21 can be started by tilting the foot pedal 24 in one direction and stopped by tilting the foot pedal 24 in the opposite direction. As an example of a usable injector pump 21 in this connection one can mention an injector pump of the type used for producing bone cement as defined in U.S. patent specification 5 328 262 and sold under the product name Scan Vacuum Pump™ by the company Scandimed International AB, Sjöbo, Sweden.

The injector pump 21 is preferably provided to generate a vacuum in all the holes 5 of the spongy bone 1 such that said holes are filled or can be filled with bone substitute and/or bone reinforcing material 3 and/ /or a vacuum such that the bone substitute and/or bone reinforcing material 3 is distributed therein, preferably without any or any substantial portions thereof being sucked into the second cannula 20.

The injector pump 21 can be provided to generate a vacuum of between -0,5 bar and -0,92 bar in the spongy bone 1, which vacuum corresponds to a 70% and 90% absolute vacuum. In many cases it is sufficient that the injector pump 21 generates a vacuum of between -0,7 bar and -0,8 bar in the spongy bone 1.

The injector pump 21 is preferably provided to suck tissue material such as blood and fat out of the holes 5 of the spongy bone 1 and into the second cannula 20 before bone substitute and/or bone reinforcing material 3 is sucked into the spongy bone 1 through the first cannula 19.

In at least one connecting conduit 25 between the second cannula 20 (the inlet end of which is the end which is inserted into a hole 5 of the spongy bone 1) and the injector pump 21, there may be provided a non-

-return valve device 26 and/or a collecting device 27 and/or a monomer filter 28 (if the bone substitute and/ /or bone reinforcing material 3 is of bone cement type) and/or a bacteria filter 29.

The collecting device 27 may be a container which is placed on the floor and closed or sealed by means of a cap. A portion of the connecting conduit 25, which is connected to the second cannula 20, is directed through the cap and a small distance down into the container. Another portion of the connecting conduit 25 is also directed through the cap and a small distance down into the container. When tissue material is sucked from the holes 5 of the spongy bone 1 to the collecting device 27, said material is collected down below in the container and is therefore prevented from being sucked further towards the injector pump 21 and into said pump. If there is a monomer filter 28 and/or a bacteria filter 29 between the collecting device 27 and the injector pump 21, the tissue material is prevented also from being sucked thereto.

The monomer filter 28 may be a carbon filter and is adapted to prevent monomer gases, generated during production of bone substitute and/or bone reinforcing material 3 in the form of bone cement, from being sucked into the injector pump 21 and discharged to the surroundings. The advantages with such a monomer filter 28 are described in the publication according to the enclosed reference list, point 4. The bacteria filter 29 is provided to prevent bacteria from entering or getting into the holes 5 of the spongy bone 1 if the connecting conduit 25 is opened or opens unintentionally and air is sucked therethrough to the holes 5 if there is a vacuum therein.

The monomer filter 28 and bacteria filter 29 may be provided in that portion of the connecting conduit 25 which connects the collecting device 27 with the injector pump 21.

The non-return valve device 26, which preferably can be provided in the connecting conduit 25 between the collecting device 27 and the second cannula 20, is adapted to prevent tissue material from being sucked out of the collecting device 27 and into the holes 5 of the spongy bone 1 if the connecting conduit 25 is opened or opens unintentionally such that a suction is generated therein towards the holes 5 of the spongy bone 1 if there is a vacuum therein.

The container 18 may include a feeding device 30 for feeding bone substitute and/or bone reinforcing material 3 out of the container 18 and into the holes 5 of the spongy bone 1 at the same time the injector pump 21 generates a vacuum therein or thereafter.

The feeding device 30 is schematically illustrated with a feed means 31 which is displaceably mounted relative to the container 18 and which can be displaced manually for discharge of bone substitute and/or bone reinforcing material 3 from the container 18 and through the first cannula 19 into the holes 5 of the spongy bone 1.

The container 18 may eventually be used as mixing container for mixing the components required for the production of such bone substitute and/or bone reinforcing material 3 that can be brought to harden after insertion thereof into the holes 5 of the spongy bone 1. This mixing can occur with a mixing means or in any other way. Such a mixing means can preferably be moved manually back and forth in the container 18 and is eventually rotated relative thereto for mixing the components.

A valve device 32 may be provided for, on one hand, close or interrupt the supply of bone substitute and/or bone reinforcing material 3 through the first cannula 19 to the holes 5 of the spongy bone 1 until the injector pump 21 has generated a suitable vacuum therein. When this is done, the valve device 32 may be opened for permitting suction of bone substitute and/or bone reinforcing

material 3 into the holes 5 of the spongy bone 1 by means of the injector pump 21. The valve device 32 may be located on the first cannula 19 or on a connecting conduit between the container 18 and the first cannula 19. The valve device 32 may be manually operable by means of a control handle 33.

As an alternative to the embodiment of the flushing or rinsing device 6 described above, said device may be combined with the supply device 8. At this alternative, the rinsing agent container 16 of the rinsing device 6 may be connected to the first cannula 19 e.g. through the valve device 32 which in this case can be a three way valve permitting either that the supply of rinsing agent to the vertebra 2 is open and the supply of bone substitute and/or bone reinforcing material 3 to the vertebra 2 is closed or that said supply of rinsing agent is interrupted and said supply of material open.

The rinsing agent 7 may be of different types and it may e.g. be distilled water or a sodium chloride solution and/or be detergent and/or include at least one trombolytic substance, e.g. heparin, streptokinase, urokinase, TPA and/or other substances dissolving coagulum and thrombi.

The bone substitute and/or bone reinforcing material 3 may consist of primarily minerals or ceramics which can be mixed with a hardener, e.g. water. These substances may be selected from the group comprising calcium sulphate-α-hemihydrate, calcium sulphate-β-hemihydrate, calcium sulphate-dihydrate, calcium carbonate, α-tricalcium phosphate, hydroxyapatite, dicalcium phosphate-dihydrate, anhydrous dicalcium phosphate, tetracalcium phosphate, β-tricalcium phosphate, calcium deficient hydroxyapatite, monocalcium phosphate-monohydrate, monocalcium phosphate, calcium-pyurophosphate, precipitated hydroxyapatite, carbonaceous apatite (dahlite), octa-

calcium phosphate, amorphous calcium phosphate, oxyapatite, carbonato apatite and calcium aluminate.

A ceramic material may be calcium aluminate, which forms part of the product Doxa T from the company Doxa (www.doxa.se/pdf/nyhet_1.pdf).

X-ray contrast agents can be added to said ceramic bone substitute and/or bone reinforcing material 3, e.g. water soluble non-ionic X-ray contrast agents selected from the group comprising iohexol, ioversol, iopamidol, iotrolan, metrizamide, iodecimol, ioglucol, ioglucamide, ioglunide, iogulamide, iomeprol, iopentol, iopromide, iosarcol, iosimide, iotusal, ioxilan, iofrotal and iodecol.

Alternatively, the bone substitute and/or bone reinforcing material 3 can be a hardenable bone cement comprising polymer and monomer components. The polymer may be polymethylmethacrylate (PMMA) and the monomer methylmethacrylate (MMA). A polymer base material can be the product Cortoss™ from the company Orthovita in the U.S.. For composition see www.orthovita.com/products/cortoss/oustechspecs.html. Another polymer base material can be the product SECOUR® Acrylic Resin PMMA from parallax medical inc. (www.parallax-medical.com/go/9192b550-5642-1157-a432-d7a2b98310fe).

The bone substitute and/or bone reinforcing material 3 may consist of a mineral and/or a ceramic in combination with polymer material.

The advantages with the invention is obvious when comparing the degree or ratio of fullness of the vertebra 2 of figs. 4 and 5. In the vertebra 2 of fig. 4, the bone substitute and/or bone reinforcing material 3 has been pressed into said vertebra 2 through a cannula or needle and it clearly appears from fig. 4 that only a part of the vertebra 2 is filled with bone substitute and/or bone reinforcing material 3. In the vertebra 2 of fig. 5 however, the bone substitute and/or bone reinforcing material 3 has been sucked into the vertebra 2 in

accordance with the invention through the cannula or needle and it is clearly evident from fig. 5 that substantially larger parts of the vertebra 2 are filled with bone substitute and/or bone reinforcing material 3 without said material having been pressed out into the blood paths.

It is also obvious from fig. 5 that the negative pressure generated by the vacuum source 9 has provided for a uniform and complete distribution of the bone substitute and/or bone reinforcing material 3 in the hole 5 and depressions 5b in the sides 5a of the hole 5.

The invention is not limited to what is described above and illustrated in the drawings, but may vary within the scope of subsequent claims. Thus, the vacuum source 9 may instead of an injector pump 21 be another vacuum pump which can be electrically operated or operated by gas or by hand or operated in any other way, that the hole 5 may be more than one hole and surrounding parts thereto, that the rinsing agent 7 may be another than those described and that the bone substitute and/or bone reinforcing material 3 may be of another type than those described.

There may be a device for imparting pulse like suction and/or insertion movements to the bone substitute and/or bone reinforcing material 3 into the hole(s) 5 in the spongy bone 1. Furthermore, there may be a device for imparting reciprocating suction and/or insertion movements to the bone substitute and/or bone reinforcing material 3 into the hole(s) 5 in the spongy bone 1.

There may also be a device for pulse like suction and/or feeding of the rinsing agent 7 through the hole(s) 5 in the spongy bone 1.

Said device may be defined by pulsating the vacuum source 9 and/or its vacuum generation and/or by generating pulses by means of the feeding device 30.

Reference list

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